

May 12, 2006

Mark Bradley, Associate Deputy Administrator  
USDA-AMS-TMP-NOP  
Room 4008-South Building  
1400 Independence Avenue, SW  
Washington, DC 20250-0020

Comments on: Docket TM-06-06-PR

Dear Mr. Bradley,

I would like to thank the USDA for posting this proposed rule to address the court mandated regulatory changes of June 9, 2004 as well as those required due to Congressional action on Nov. 10, 2005, amending the Organic Foods Production Act (OFPA).

I am commenting here as one concerned individual, not as a representative of the Independent Organic Inspectors Association.

I am concerned that the language as proposed is not clear and does not resolve all of the issues addressed in the court ruling and Congressional amendment. If implemented as proposed, the rule change is likely to cause inconsistent implementation of the USDA regulation for organic production and handling.

I offer the following detailed comments on two issues: Synthetic ingredients in processed organic foods and transition for dairy herds.

### Synthetic Substances

The docket incorrectly states that "USDA will not have to revise the NOP regulations" regarding the use of synthetic substances used during the processing of organic products.

Docket TM-06-06-PR, in the fourth paragraph of page 4, states, "On November 10, 2005, Congress amended the OFPA by permitting the addition of synthetic substances appearing on the National List for use in products labeled "organic.""

Actually, Congress amended OFPA to allow synthetic *ingredients* on the National List, not synthetic *substances*.

On November 10, 2005, Congress amended Section 2111 (7 U.S.C. 6510) of the OFPA, to read, "(a) IN GENERAL. - For a handling operation to be certified under this title, each person on such handling operation shall not, with respect to any agricultural product covered by this title -

(1) add any synthetic ingredient not appearing on the National List during the

processing or any postharvest handling of the product;"

It is important to note that Congress did not amend Section 2105 (6504) of OFPA, which reads, "to be sold or labeled as an organically produced agricultural product under this title, an agricultural products shall - (1) have been produced and handled without the use of synthetic chemicals, except as otherwise provided in this title."

As amended, there is no allowance in OFPA for the use of synthetic substances during handling, except for the use of synthetic *ingredients* that are on the National List [7 U.S.C. 6510(a)(1)]. Other synthetic substances, unless classified as *ingredients* under the Act and regulation, remain prohibited during handling.

This topic was addressed on page 3, paragraph 2, of the Consent Final Judgment and Order, June 9, 2005, which states, "With respect to Count 3, 7 C.F.R §§ 205.600(b) and 605(b) are contrary to the OFPA and exceed the Secretary's rulemaking authority to the extent that they permit the addition of synthetic ingredients and processing aids in handling and processing of products which contain a minimum of 95% organic content and which are eligible to bear the USDA seal."

In order to allow the continued use of synthetic substances, such as processing aids and adjuvants, and to protect the USDA from future legal action, USDA must clarify through rulemaking and guidance, that all substances used in or on processed organic products, which have direct contact with organic processed products, are categorized as "ingredients" under regulations implementing the OFPA. All such ingredients must be subject to the National List process.

The definition of "ingredient" should be revised to be consistent with references to ingredients and substances used during the processing of organic products found at §205.105, §205.270(b), §205.301(b), and §205.605.

The Department still has a policy statement entitled, "*Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board When Such Substances are Used as Ingredients in Processed Food Products*" posted on the NOP website which specifically exempts an entire class of FDA-listed "Food Contact Substances" from the National List process and NOSB review. [Go to [www.cfsan.fda.gov/%7Edms/opa-fcn.html](http://www.cfsan.fda.gov/%7Edms/opa-fcn.html) to see the list of Food Contact Substances]

The NOP's Food Contact Substance policy statement is in direct conflict with the OFPA and the Court's Consent Final Judgment and Order.

In its court filings, the USDA admitted that the current Food Contact Substance policy is not final, "was posted for discussion," and "is part of an ongoing deliberation about how the Act and Rule operate." [Brief of Appellee at 23-24, n.

11, Harvey v. Veneman, 396 F.3d 28 (1st Cir. 2005) (No. 04-1379).]

### Recommended Actions

- 1) The USDA should withdraw the Policy Statement of December 12, 2002, entitled, "*Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board When Such Substances are Used as Ingredients in Processed Food Products.*"
- 2) The USDA should issue a Policy Statement affirming that all substances used in or on processed organic products, which have direct contact with processed organic products, are considered ingredients under the OFPA and its implementing regulations. As such, all substances used in or on processed organic products are subject to National List procedures and must be reviewed by the National Organic Standards Board.
- 3) The USDA should conduct rulemaking to amend the definition of "ingredient" to assure that all substances used in or on processed organic products are considered ingredients under the OFPA. The definition of "ingredient" should be amended to read:

#### **"§205.2 Terms defined Ingredient.**

Any substance which has direct contact with processed products used in or on the preparation of an organic agricultural product ~~that is still present in the final commercial product as consumed.~~"

### Criteria for Review of Synthetic Ingredients

As mentioned above, the Consent Final Judgment and Order, June 9, 2005, states, "With respect to Count 3, 7 C.F.R §§ 205.600(b) and 605(b) are contrary to the OFPA and exceed the Secretary's rulemaking authority..."

The court found the § 205.600(b) criteria for the evaluation of synthetic ingredients and processing aids to be contrary to OFPA. The Congressional amendment did not restore the criteria.

Further, the criteria in § 205.600(b) specifically apply only to "any synthetic substance used as a *processing aid or adjuvant*." (italics added) The Final Rule contains no criteria for the evaluation of synthetic *ingredients*.

In order for the NOSB to evaluate petitioned synthetic ingredients, the criteria in § 205.600(b) must be reinstated and revised during the rulemaking process. The criteria must be amended to apply to all synthetic ingredients, rather than to synthetic processing aids and adjuvants.

### Recommended Actions

- 1) Rules need to be issued to reinstate criteria for the evaluation for all substances petitioned for use in the processing of organic products.
- 2) The criteria in §205.600(b) should be re-written to read:  
“(b) In addition to the criteria set forth in the Act, any synthetic substance used ~~as a~~ in organic processing ~~aid or adjuvant~~ will be evaluated against the following criteria:...”

### Origin of Livestock

I support changes to §205.236(a)(2) to allow the use of “crops and forage from land included in the organic system plan of a dairy farm that is in the third year of organic management,” as stated in the Congressional amendment to OFPA.

It should be noted, however, that the OFPA amendment and the new proposed rule change allow for the feeding of "crops and forages" from land in its third year of organic management, not just the grazing of pastures, as repeatedly indicated in Docket TM-06-06-PR's explanatory text (71 FR 24823).

In order to implement the new provision, and verify that crops and forages fed to dairy animals for one year prior to production of organic milk are from land that in its third year of organic management and is included in the operation's organic system plan, inspection of the operation's crops and forages during the second year of organic management is essential.

Speaking as an inspector of 19 years, I strongly encourage that new requirements be added to §205.403 to require on-site inspection of applicant dairy operations to verify compliance with §205.236(a)(2).

The language, as proposed, may inadvertently permit the use of crops and forage produced during the first two years of transition, since land that is not in third year transition, as well as stored crops and forage from previous harvests, may be “included in the organic system plan.”

I suggest a punctuation change to indicate that crops and forage must come from land that is in the third year of transition to certified organic production.

### Recommended Action

- 1) §205.403(b) should be amended by adding a new section §205.403(b)(3) to read:

“3) An on-site inspection of a dairy operation must be conducted prior to the beginning of the third year of organic management in order to verify that crops and forages, fed to dairy animals for one year prior to sale of

organic milk and milk products, are certified organic or are from land that in its third year of organic management and are included in the operation's organic system plan."

2) Commas should be inserted in § 205.236(a)(2), as indicated below, to clarify that only crops and forages from land in its third year of transition to certified organic production may be fed to dairy animals during the 12-month period prior to production of organic milk and milk products.

§ 205.236 Origin of livestock. (a)

"2) *Dairy animals* - conversion of herds. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic, Except, That, crops and forage from land, included in the organic system plan of a dairy farm, that is in the third year of organic management may be consumed by the dairy animals of the farm during the 12-month period immediately prior to the sale of organic milk and milk products."

### Conclusion

I appreciate the opportunity to submit comments to the USDA. I am concerned that the 15-day comment period was inadequate for many stakeholders.

Respectfully,

Margaret Scoles  
Organic Inspector